UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PFIZER INC.,		
	Plaintiff,	
v.		Case No.: 14 CV 4659 (ALC)
MCNEIL-PPC, INC.,		
	Defendant.	

MEMORANDUM OF LAW IN OPPOSITION TO MCNEIL'S MOTION TO DISMISS

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PRELIMINARY STATEMENT

Plaintiff Pfizer Inc. ("Pfizer") properly seeks a declaration regarding the scope of a 1989 Consent Final Judgment (the "Consent Judgment") to stop Defendant McNeil-PPC, Inc. ("McNeil") from unfairly threatening Pfizer with contempt based on an improper expansion of the Consent Judgment. Pfizer pleaded a claim for relief based on the parties' real and immediate dispute, warranting this Court's adjudication. McNeil's motion to dismiss should be denied.

Pfizer, the maker of Advil products, and McNeil, the maker of Tylenol products, are long-standing competitors in the over-the-counter ("OTC") analgesic and fever-reducing markets. McNeil is trying to gain an unfair advantage, however, in the pediatric market. It is making unfounded threats of contempt in order to stifle Pfizer's dissemination of accurate information to doctors about clinical studies on the effects of ibuprofen in infants. The information Pfizer wants to share is valuable to doctors in making informed choices about which analgesic and fever-reducer to recommend for their pediatric patients.

Pfizer brought this action in response to a cease-and-desist letter from McNeil regarding an October 2013 advertisement for Infants' Advil that Pfizer ran in medical journals (the "Infants' Advil Ad"). The advertisement correctly reported that a large study showed that infants taking ibuprofen and infants taking acetaminophen experienced a "comparable incidence of digestive system adverse events overall." Am. Compl., Ex. B. In its letter, McNeil claimed that the Consent Judgment, which the parties' predecessors negotiated in 1989 to settle their false advertising claims about products that had been approved only for use in adults, applies to advertising for pediatric products and prohibits the ad. McNeil thus improperly attempted to expand the Consent Judgment's scope, and Pfizer filed this action to resolve the dispute.

McNeil's motion seeks a rush to judgment on both the merits of Pfizer's case, as well as a

false advertising claim that McNeil has never filed. The only question that is properly before the Court now is whether Pfizer has adequately alleged a claim that would entitle it to relief taking all its allegations as true. Here, Pfizer alleges that the Consent Judgment does not apply to pediatric products, the underlying litigation in the 1980s did not pertain to pediatric products, the prior court did not adjudicate facts and law regarding pediatric products, and the parties involved did not intend the Consent Judgment to apply to pediatric products. Taking all these allegations as true, Pfizer has more than adequately alleged a basis to have this Court issue the relief it seeks: a declaration that the Consent Judgment does not apply to pediatric products.

McNeil disputes the truth of the allegations, rather than their sufficiency. It says that the Court does not have to accept any of the allegations as true because the Court can read the Consent Judgment for itself. McNeil is correct that the Court can review the language of the Consent Judgment, but McNeil's reading of the Consent Judgment is simply wrong. The plain language of the Consent Judgment favors Pfizer: "Advil" in 1989 could not possibly have included pediatric ibuprofen products because *no such products existed at the time*. The Consent Judgment includes no language covering future products, which the law requires for a contract (such as a consent judgment) to apply to such products. Further, the Amended Complaint contains supporting allegations about the circumstances surrounding the Consent Judgment's formation, including that the litigation that led to the Consent Judgment involved only (1) products approved for use in adults, (2) advertisements about such products and their safety and efficacy in adults, and (3) clinical data about the effects of such products on adults. McNeil wrongly asks the Court to ignore all of these allegations that weigh heavily in favor of Pfizer.

In light of the plain language of the Consent Judgment, the Court could find for Pfizer on its claim that pediatric Advil products are not encompassed by the Consent Judgment. If the

Court, however, believes there is ambiguity as to whether the term "Advil" in the Consent Judgment includes products other than those that existed at the time, Pfizer is entitled to present extrinsic evidence to prove its allegations about the parties' intent, the issues in the 1980s litigations, the drafting and entry of the terms of the Consent Judgment, the post-entry development and FDA approval of the pediatric products, and the parties' subsequent course of dealing with regard to pediatric advertising and the reach of the Consent Judgment.[1] Moreover, the law is clear that the broader interpretation of an ambiguous consent order should be rejected absent a clear manifestation of intent.

McNeil's argument that the Court should rule in its favor because, according to McNeil, all ibuprofen products have the same "mechanism of action" (prostaglandin inhibition) and will thus always cause more adverse gastrointestinal ("GI") effects on consumers than acetaminophen products only highlights the impropriety of McNeil's attempt to prematurely adjudicate the merits of this case. The prior court made no findings and reached no conclusions about the GI effects of ibuprofen on children and infants because the issue was not before it 25 years ago. Undoubtedly, a motion to dismiss is not the proper vehicle for deciding the physiological impact of ibuprofen on the human body and whether it differs on the bodies of children and infants than adults (which it does) and therefore is observed in clinical studies in pediatric populations to have a different outcome with respect to GI effects (which it does).

Indeed, as Pfizer alleges, in the 1990s, the FDA required new studies focused only on children and infants before it would approve OTC pediatric ibuprofen products. As a result,

[1] Contrary to McNeil's argument, Pfizer's claim does not require the Court to determine whether an ad is truthful, or whether the science substantiates a claim. Nor will granting the relief requested by Pfizer result in a free license for Pfizer to make false and misleading claims that will put children at risk. If the Court ultimately agrees with Pfizer's interpretation, Pfizer will still be required by law to run truthful, non-misleading ads. If McNeil believes that a particular ad for a Pediatric Advil product is false or misleading, it can bring a claim for false advertising and prove it is right, rather than make unfounded blanket threats of contempt.

Pfizer's predecessor conducted the Children's Analgesic Medicine Project ("CAMP"), an actual-use trial involving more than 41,000 children to compare the safety of Children's Advil (then a prescription-only product) and Children's Tylenol. This was required because the FDA—and the medical community in general—recognizes that children are not "little adults." McNeil's request that this Court assume that ibuprofen has the same safety profile in children as it does in adults flies in the face of this medical truth and would lead the Court into making a dangerous and flawed ruling about how medicines work—all on a motion to dismiss.

As part of its effort to prevent Pfizer from presenting its case, McNeil also continues to argue that somehow—despite its cease-and-desist letter—Pfizer has not stated a justiciable controversy. In order to not burden the Court with technical arguments about Pfizer's choice of words, Pfizer amended its complaint to include the exact words which, according to McNeil's original motion to dismiss, were lacking. McNeil should have moved on, but instead continues to argue that this dispute is not sufficiently immediate because Pfizer alleges that it will await the resolution of its claim before re-running the challenged advertisement. The law is clear, however, that Pfizer need not risk contempt proceedings to state a claim. Pfizer's decision to seek a legal resolution of the parties' dispute is exactly the appropriate course.

Justice and due process require that litigants be given the chance to develop their case when they have stated a *prima facie* valid cause of action. Pfizer has laid out the basis for a declaration in its favor based on the unambiguous language of the Consent Judgment. If the Court does not believe that the Consent Judgment unambiguously includes only Adult Advil, Pfizer should be allowed to take discovery, marshal the facts in its favor, and submit an organized presentation to the Court before the merits are adjudicated. McNeil's motion to rush the final decision in this case is procedurally improper and should be denied.

STATEMENT OF FACTS

I. THE INTRODUCTION OF ADULT ADVIL AND THE SUBSEQUENT 1985 LITIGATION ABOUT ADS FOR ADULT PRODUCTS

In 1984, shortly after receiving FDA approval, American Home Products Corporation ("AHP"), a predecessor of Pfizer, introduced Advil as an adult ibuprofen product ("Adult Advil").[2] Am. Compl. ¶ 24. At the time, a McNeil predecessor was the manufacturer of Tylenol, an acetaminophen-based analgesic for adults ("Adult Tylenol"). *See Am. Home Prods. Corp. v. Johnson & Johnson*, 654 F. Supp. 568, 573 (S.D.N.Y. 1987).

After AHP's launch of Adult Advil, McNeil started a campaign comparing the safety profiles of leading OTC analgesic products. Am. Compl. ¶ 26. In 1985, AHP filed a false advertising suit against McNeil for falsely conflating the safety of Adult Advil with that of aspirin, and making false, unfavorable comparisons of the safety profiles of Adult Advil and aspirin with that of Adult Tylenol (the "1985 Litigation"). *Id.*; *see also* 654 F. Supp. at 572. AHP claimed that Adult Advil was as good as or better than Adult Tylenol with respect to most of the adverse effects at issue, and that Adult Advil was better than aspirin with respect to them all. 654 F. Supp. at 575. McNeil counterclaimed that certain of AHP's advertisements for Adult Advil and two other OTC adult medications made false comparative claims. *Id.* at 586–89.

AHP's complaint defined the initial key terms for the litigation, including "Advil":

> American Home Products manufactures and sells for resale to consumers ADVIL, a nonprescription internal analgesic containing 200 mg. of ibuprofen per tablet that was approved by the Food and Drug Administration for OTC sale on May 18, 1984.

[2] In this brief, "adult(s)" means people ages 12 and over, which reflects the Adult Advil and Adult Tylenol labels. *See* Am. Compl. ¶ 3. Children's Advil products are for ages 2 to 11, and Infants' Advil is for ages 6 to 23 months (collectively, "Pediatric Advil"). *See id.*

Declaration of Dale M. Cendali, Esq. ("Cendali Decl."), Ex. 1, ¶ 2.[3] This clearly refers to the Adult Advil that existed at the time, which was approved by the FDA in 1984 for OTC sale in 200 mg tablets. *See* Def. Br. 7 ("Conventional Advil tablets . . . contain 200 mg of ibuprofen . . . ."); Am. Compl. ¶ 24. It certainly does not refer to Children's Advil, a liquid product, which was first approved for OTC sale in 1996, or to Infants' Advil, a concentrated liquid drop product, which was first approved for OTC sale in 1998.[4] Am. Compl. ¶¶ 8, 37–38, 41.[5]

The 1985 Litigation culminated in a four-week bench trial before Judge William C. Conner, who heard testimony from dozens of witnesses, including physicians and researchers specializing in pharmacology, gastroenterology, hematology, epidemiology, and the systemic effects of analgesics. 654 F. Supp. at 572. No testimony was presented about the comparative GI effects of ibuprofen versus acetaminophen in children or infants. Am. Compl. ¶ 39.

At trial, Judge Conner examined evidence related to adverse effects to determine whether acetaminophen or ibuprofen had a superior safety profile in relation to various effects. The evidence presented at trial (including expert testimony, consumer surveys, scientific data, and clinical studies) only related to the effects of aspirin, ibuprofen and acetaminophen in adults, and

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[3] Courts may take judicial notice of any fact not subject to reasonable dispute that either "(1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Therefore, court records and transcripts are subject to judicial notice. *See, e.g.*, *Hayes v. Perotta*, 751 F. Supp. 2d 597, 599 (S.D.N.Y. 2010).

[4] Children's Advil was not approved even as a *prescription medicine* until late 1989, several months after the Consent Judgment was entered. Am. Compl. ¶ 7.

[5] In an effort to equate Adult Advil and Pediatric Advil products, McNeil incorrectly states that the recommended dose of Adult Advil is "*the same as*" the recommended dose of Junior Strength Advil, a Pediatric Advil product approved for OTC use in children ages 6 to 11. Def. Br. 7. In fact, the recommended dose for adults is *two tablets* of Adult Advil (a total of 400 mg) if pain and fever persists, which is more than the recommended doses of Junior Strength Advil for children (2 or 3 tablets containing 100 mg depending on the child's weight and age). *See Am. Home Prods.*, 654 F. Supp. at 585–86 (rejecting McNeil's argument that "one tablet of Advil (200 mg.)" is the recommended dose of Adult Advil because "the FDA-approved instructions . . . recommend taking 400 mg. . . . if 200 mg. fails to give the desired relief"). Also, the Adult Advil label permits dosing every four to six hours compared to a lower frequency of every six to eight hours for Children's Advil, Infants' Advil, and Junior Strength Advil products. Cendali Decl., Exs. 6–9.

involved only adult dosages and populations.[6] 654 F. Supp. 568; Am. Compl. ¶ 27.

On February 25, 1987, Judge Conner ruled that certain claims made by McNeil and AHP about Adult Tylenol and Adult Advil, respectively, were misleading. The court made many findings of fact regarding the incidence of adverse effects caused by these products. 654 F. Supp. at 591; Am. Compl. ¶ 28. Two such findings are pertinent here. First, Judge Conner found that the products carry similarly low risks of causing "stomach upset" in adults, which he referred to as "*subjective* gastrointestinal symptoms of physical discomfort, such as dyspepsia, nausea, flatulence, heartburn and diarrhea." 654 F. Supp. at 583; Am. Compl. ¶ 28. Second, Judge Conner found that acetaminophen posed a lower risk of "*objective* gastrointestinal side effects, such as ulceration, hemorrhage and occult bleeding" in adults than ibuprofen. *Id.*

II. THE 1987 LITIGATION REGARDING ADS FOR ADULT ADVIL AND THE ENTRY OF THE CONSENT JUDGMENT

After the decision in the 1985 Litigation, which as noted above found that the products carried similarly low risk of stomach upset, AHP began running consumer television advertisements for Adult Advil that stated: "Like Tylenol, Advil doesn't upset my stomach." *McNeilab, Inc. v. Am. Home Prods. Corp.*, 675 F. Supp. 819, 820 (S.D.N.Y. 1987); Am. Compl. ¶ 29. In May 1987, McNeil sued AHP over these advertisements (the "1987 Litigation"). *Id.*

The complaint filed by McNeil in the 1987 Litigation identifies the product at issue as Adult Advil by stating: "In the Spring of 1984, AHP introduced a new OTC internal analgesic under the name ADVIL." Cendali Decl., Ex. 2, ¶ 7. Again, this clearly referred to Adult Advil, which was introduced in 1984 for OTC sale, and could not have been a reference to Pediatric

[6] The only references to children in the 1985 Litigation are in a discussion of overdose with acetaminophen by children, and a tangential reference to two "idiosyncratic" case reports of liver damage in children who ingested prescription-strength ibuprofen. 654 F. Supp. at 589; 1985 Litigation Tr. at 441:1-25; 478:4-7. However, no safety studies on ibuprofen use in children, much less any studies comparing the adverse effects of ibuprofen and acetaminophen in children, were presented. 1985 Litigation Tr. at 2129:21-35.

Advil, which did not exist as a product yet.[7] Def. Br. 11; Am. Compl. ¶ 33. Moreover, the advertisements challenged by McNeil and attached to its Complaint were about use of Adult Advil by adults. Cendali Decl., Ex. 2.

The 1987 Litigation was a direct outgrowth of Judge Conner's decision in the 1985 Litigation. McNeil contended that AHP's new advertisements did not accurately reflect Judge Conner's findings because the ads created the implied misimpression that Adult Advil is equivalent to Adult Tylenol with respect to all GI effects (including *objective* GI symptoms), not just stomach distress (*i.e.*, *subjective* GI symptoms). 675 F. Supp. at 820–22; Am. Compl. ¶ 30. AHP claimed that its ads made clear that the "like Tylenol" claim referred to minor, subjective stomach upset and was consistent with Judge Conner's earlier decision. 675 F. Supp. at 821.

The parties did not relitigate the scientific issues from the 1985 Litigation. Because the issue in that case was consumers' likely interpretation of advertisements, the key evidence in the 1987 Litigation consisted of consumer surveys, which were conducted on adults who were the target purchasers of Adult Advil. 675 F. Supp. at 821–23. No studies of ibuprofen in pediatric populations were presented or even referred to in the 1987 Litigation. Am. Compl. ¶ 33.

On December 1, 1987, Judge Conner found that McNeil was likely to show that the impression generated by AHP's ads was misleading in light of the findings in the 1985 Litigation regarding the objective GI effects of Adult Advil and Adult Tylenol, and therefore granted McNeil's motion for a preliminary injunction. 675 F. Supp. at 826; Am. Compl. ¶ 31.

The parties settled after an appeal, preempting a trial on the merits. Cendali Decl., Ex. 3. As part of the settlement, the parties negotiated two Consent Final Judgments, one for the 1985

[7] McNeil's reference to a notation on Adult Advil's label advising consumers to "ask a doctor" before giving to children under 12 is a red herring. Def. Br. 5. This case is about whether the Consent Judgment covers Pediatric Advil products, not whether Adult Advil can conceivably be given to children. Adult Advil is *not* intended or labeled for children under the age of 12—the instructions for use only pertain to adults using the product.

Litigation and a second for the 1987 Litigation, both of which were entered on March 31, 1989. Am. Compl. ¶ 31. The Consent Judgment at issue here (from the 1987 Litigation) states that AHP is "permanently enjoined from stating in words or substance in any advertisement that ADVIL is 'like TYLENOL' in the respect of adverse effects on the stomach . . . ." *Id.* ¶ 32.

III. PFIZER'S SUBSEQUENT ADVERTISEMENTS FOR PEDIATRIC PRODUCTS

McNeil claims that the 1989 Consent Judgments have governed the parties' advertising for all Advil products—including all Pediatric Advil products—for 25 years. Def. Br. 1–2. The Court, however, cannot accept such outside-the-pleading contentions on a Rule 12(b)(6) motion. Indeed, the discovery will show that Pfizer ran advertisements before October 2013 that truthfully stated that Children's Advil is as safe as Children's Tylenol with respect to GI effects and that Pfizer has previously contended that pediatric products are not covered by the Consent Judgment. This factual dispute shows that it would be improper to accept McNeil's (false) assertions about past conduct on a motion to dismiss.

The current dispute is based on Pfizer's October 2013 advertisement in medical journals for Infants' Advil that accurately cited a medical journal article (the "Ashraf Article") reporting on CAMP.[8] Am. Compl., Ex. B. The Ashraf Article reported that there was no statistically significant difference in the incident rates of "any" digestive adverse events—a category encompassing all types of adverse events affecting the digestive system—between infants taking ibuprofen and those taking acetaminophen in the CAMP study. *Id.*, Ex. B at Table 3. The Infants' Advil Ad accurately reported the Ashraf Article's finding that ibuprofen, the active ingredient in Infants' Advil, had a "comparable incidence of digestive system adverse events overall" to acetaminophen, the active ingredient in Infants' Tylenol. *Id.* ¶ 43.

[8] E. Ashraf, *et al.*, *Safety Profile of Ibuprofen Suspension in Young Children*, 7 IMMUNOPHARMACOLOGY 219 (1999).

On November 22, 2013, McNeil sent a cease-and-desist letter to Pfizer, demanding that the Infants' Advil Ad "be immediately discontinued" because the Consent Judgment purportedly applies and bars Pfizer from making any claims of GI comparability for infants' products. Am. Compl., Ex. C. On December 6, 2013, Pfizer responded to McNeil and disagreed with McNeil's broad interpretation of the Consent Judgment. *Id.* ¶ 45, Ex. D. Pfizer nevertheless agreed to discontinue the Infants' Advil Ad pending further consideration and reserved its rights on the issue of whether the Consent Judgment is applicable. *Id.* ¶ 46. On June 25, 2014, Pfizer brought this action seeking a declaration that the Consent Judgment does not apply to Pediatric Advil. *Id.* ¶ 15. Pfizer is prepared and intends to re-run the Infants' Advil Ad if the Court resolves the present dispute in Pfizer's favor. *Id.* ¶ 47.

ARGUMENT

On a motion to dismiss, the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *See Pearson Educ., Inc. v. Boundless Learning, Inc.*, 919 F. Supp. 2d 434, 436 (S.D.N.Y. 2013) (Carter, J.). To survive a motion to dismiss, all a plaintiff must do is allege a claim to relief that is plausible on its face. *Id.* The issue before the Court in deciding such a motion "'is not whether . . . plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *Id.* at 437 (quoting *Villager Pond, Inc. v. Town of Darien*, 565 F.3d 375, 378 (2d Cir. 1995)).

The Amended Complaint adequately alleges that Pfizer is entitled to the declaration it seeks because the Consent Judgment does not apply to ads about pediatric products. Pfizer's interpretation is supported by the plain language of the Consent Judgment and the circumstances surrounding its formation. Moreover, if the Court finds that the Consent Judgment is ambiguous, the motion must be denied so the parties can present evidence regarding the parties' intent.

If Pfizer's allegations are true, then Pfizer is entitled to the declaratory judgment it requested. McNeil disputes Pfizer's interpretation of the Consent Judgment but does so based on a number of factual assertions that are not alleged in the Amended Complaint and, accordingly, are not properly considered on a motion to dismiss. McNeil goes so far as to devote a substantial portion of its motion to an argument concerning the underlying substantive truth or falsity of the Infants' Advil Ad (again relying on factual assertions that are not alleged in the Amended Complaint). The truth of the Infants' Advil Ad, however, is not part of the Amended Complaint, and is certainly not an issue that could be resolved on a motion to dismiss.

I. THE AMENDED COMPLAINT APPROPRIATELY SEEKS A JUDICIAL DECLARATION REGARDING THE SCOPE OF THE CONSENT JUDGMENT

McNeil's primary argument in its motion is that Pfizer is wrong that the Consent Judgment does not apply to Pediatric Advil. The only way McNeil could prevail on this theory on a motion to dismiss is if it could show, based *solely* on the facts alleged in the Amended Complaint, that the Consent Judgment *unambiguously* encompasses pediatric products. McNeil has not even attempted to do so. Its motion is filled with McNeil's own outside-the-record factual assertions regarding the 1980s litigations—assertions that Pfizer disputes.

As McNeil concedes, the Consent Judgment must be interpreted like a contract. Def. Br. 14. Pfizer contends that the word "Advil" in the Consent Judgment could not possibly refer to pediatric products because the first such OTC product would not be approved until seven years after entry of the Consent Judgment, and there is no reference in the Consent Judgment to products developed in the future. While McNeil disagrees, the most it has done is to raise the issue of whether the Consent Judgment is ambiguous. Contract language is ambiguous if it "could suggest more than one meaning when viewed objectively by a reasonably intelligent person who has examined the context of the entire integrated agreement and who is cognizant of

the customs, practices, usages and terminology as generally understood in the particular trade or business." *Int'l Multifoods Corp. v. Commercial Union Ins. Co.*, 309 F.3d 76, 83 (2d Cir. 2002) (internal quotation marks omitted). To determine if a consent order is ambiguous, courts consider its plain language and the circumstances surrounding its formation. *See id.* at 85–86 (considering the plain language); *Whitmire v. Corbel & Co.*, 977 F. Supp. 290, 293 (S.D.N.Y. 1997) (noting that courts consider "the circumstances surrounding the formation of the consent judgment" to interpret its meaning); *Escalera v. N.Y. Hous. Auth.*, 924 F. Supp. 1323, 1336 (S.D.N.Y. 1996) ("[T]he scope of a consent decree must be discerned within its four corners.") (internal quotation marks omitted); *Coca-Cola Bottling Co. of Elizabethtown, Inc. v. Coca-Cola Co.*, 769 F. Supp. 599, 615 (D. Del. 1991) (stating that considering "circumstances surrounding the formation of the consent order . . . does not depart from the 'four corners' rule").

If a contract is ambiguous, it cannot be interpreted as a matter of law on a motion to dismiss. *Random House, Inc. v. Rosetta Books, LLC*, 150 F. Supp. 2d 613, 618 (S.D.N.Y. 2001). In such a case, "interpretation of the contract becomes a question of fact for the finder of fact and extrinsic evidence is admissible." *Id.* Using these tools of interpretation, "Advil" in the Consent Judgment does not and could not encompass pediatric products.

A. Pfizer's Allegations Demonstrate that the Consent Judgment Does Not Include Pediatric Products

1. The Plain Language of the Consent Judgment Shows that It Does Not Include Pediatric Products

According to its plain language, the Consent Judgment does not encompass pediatric products. As McNeil concedes, the Consent Judgment incorporates Judge Conner's Opinion and Order dated December 1, 1987. Def. Br. 15; Am. Compl., Ex. A. In that Opinion and Order, Judge Conner described "Advil" using the present tense: "Defendant American Home Products ('AHP') *manufactures and sells* . . . an OTC internal analgesic, Advil, whose principal active

ingredient is ibuprofen." *McNeilab*, 675 F. Supp. at 820 (emphasis added). Judge Conner also used the present tense when referring to "Advil" in his earlier opinion from the related 1985 Litigation: "[AHP] *markets* the OTC analgesic ibuprofen under its trademark Advil." *Am. Home Prods.*, 654 F. Supp. at 572 (emphasis added).

It is well-settled that use of the present tense limits the scope to only those items that could be described by the language at the time the contract or consent order issued and excludes future items. *See VKK Corp. v. Nat'l Football League*, 244 F.3d 114, 130 (2d Cir. 2001) (reversing finding that agreement covered affiliates that joined the NFL after agreement was signed because the "reference to 'affiliates' and the definition of the word are stated in the present tense"); *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 361 F. Supp. 2d 210, 215 (S.D.N.Y. 2005) (license applies only to patents owned at the time of agreement because it described patents by stating that the licensor "*is* the owner of the rights" and there was no reference to later-acquired patents); *see also Wi-LAN USA, Inc. v. Ericsson, Inc.*, 574 Fed. Appx. 931, 939 (Fed. Cir. 2014) (contract referring to patents that one party "*owns* or *controls*" covered only patents owned or controlled at the time the contract was formed because "the use of the present tense means that the [agreement] does not apply to later acquired patents").

Here, as Pfizer alleges, at the time the parties entered into the Consent Judgment, no pediatric ibuprofen products had been approved by the FDA—either by prescription or OTC—and thus no Pediatric Advil product was sold, let alone advertised. Am. Compl. ¶¶ 7, 29. Therefore, the fact that Judge Conner's described "Advil" as a product that AHP "*manufactures* and *sells*," which description was incorporated into the Consent Judgment, means that the term "Advil" does not include future Pediatric Advil products.[9]

[9] McNeil's reliance on *Wilder v. Bernstein*, 49 F.3d 69 (2d Cir. 1995), to support its argument that the Consent Judgment encompasses future products is misplaced. Def. Br. 17. In *Wilder*, the court interpreted a consent decree,

Moreover, the Consent Judgment makes no reference to Pediatric Advil products, nor does it indicate that the parties intended it to apply to future products. Am. Compl. ¶ 7. *See VKK Corp.*, 244 F.3d at 130 (finding that contract term did not encompass "completely new" teams and that the parties could have specifically provided for the inclusion of future teams); *see also Coca-Cola Bottling Co. of Shreveport v. Coca-Cola Co.*, 769 F. Supp. 671, 706 (D. Del. 1991) ("When interpreting perpetual contracts after a considerable period of time has passed since the time they were entered into, the Court resists the temptation to conform the contract to modern circumstances by adding contract terms not assented to originally.").[10]

McNeil claims that Pfizer's interpretation of the Consent Judgment would lead to an "absurd result" because the Consent Judgment would not cover certain other adult Advil-brand ibuprofen products that were not introduced or approved until after the Consent Judgment was entered. This argument is a red herring. The only issue in this case is whether the Consent Judgment covers Pediatric Advil products intended for entirely different patient populations—and not whether it applies to these other adult products. New products may have different characteristics or impact users, including infants and children, in a different biological way, so

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which was applicable to "all New York City children" in foster care, as also applying to children in "kinship foster care." *Wilder*, 49 F.3d at 73. The court stated that, "although kinship foster care did not exist in its present form" and the term was not mentioned in the consent decree, this type of foster care was nevertheless occurring at the time of the consent decree and was not legally restricted. *Id.* In contrast, no Pediatric Advil product was available or legally approved for use in children under the age of 12—even by prescription—at the time of the Consent Judgment. Am. Compl. ¶ 7. Thus, *Wilder* supports Pfizer's position.

[10] The other Consent Final Judgment—which finalized the 1985 Litigation and was negotiated by the same parties at the same time that they negotiated the Consent Judgment—included broader language that enjoined AHP from making certain claims for "Advil, any other ibuprofen products, or ibuprofen in general." Cendali Decl., Ex. 10, ¶ 6. This language confirms that "Advil" was used to refer to the existing 200 mg tablet. When the parties and the court wanted to capture other ibuprofen products that AHP had developed at the time, they expressly referred to "other ibuprofen products" or "ibuprofen in general" to include those products within the order's scope. The parties were sophisticated litigants represented by experienced counsel. They could have included broad language in the Consent Judgment to reference future products, like Pediatric Advil products, but they did not. In fact, Pediatric Tylenol was in existence at the time—and obviously known to its manufacturer McNeil—further reinforcing the conclusion that these sophisticated parties had no intention that the Consent Judgment cover pediatric products.

that extrapolation of old findings and legal conclusions to the new products is inappropriate.[11]

Finally, McNeil's argument that the Consent Judgment covers Pediatric Advil products because it prohibits Pfizer from making the prohibited claim "in words or substance" in "any advertisement" misses the point. Def. Br. 14. By using the phrase "in words or substance," the Consent Judgment prohibited AHP from making the claim that "Advil is 'like Tylenol' in the respect of adverse effects on the stomach," as well as from making other claims that convey the same message even if the words are different. The crux of the parties' current dispute is not over the words "like Tylenol," but rather, over the meaning of the terms "Advil" and "Tylenol." The "in words or substance" language does not extend the Consent Judgment to every subsequently developed medicine that uses the Advil name, regardless of its characteristics or impacts on the relevant patient population and whether the effects of its use were ever litigated.

2. The Circumstances Surrounding the Formation of the Consent Judgment Show that It Does Not Include Pediatric Products

Pfizer's allegations about the circumstances surrounding the Consent Judgment further reinforce the finding that the term "Advil" in the Consent Judgment does not unambiguously include pediatric products. As detailed below, Judge Conner did not adjudicate issues related to pediatric products or the effect of these products (or even ibuprofen generally) on infants or children. The Consent Judgment, which embodied the parties' settlement of the 1987 Litigation, therefore cannot reasonably be interpreted to apply to pediatric products. *See United States v. O'Rourke*, 943 F.2d 180, 188 (2d Cir. 1991) (finding consent decree, which resolved prior litigation about one particular landfill, should not be interpreted to cover all waste in the county).

First, as Pfizer alleges, all of the scientific and medical evidence about ibuprofen that was

[11] In all events, McNeil's effort to suggest that appropriately defining the scope of the Consent Judgment could lead to Pfizer making unsubstantiated claims is entirely without merit. The Lanham Act ensures that advertising about new products will be truthful, regardless of whether the Consent Judgment applies.

presented in the 1980s litigations, and on which Judge Conner based his decisions, involved the effects of ibuprofen on adults. 654 F. Supp. 568; 1985 Litigation Tr. at 2129:21-35; Am. Compl. ¶¶ 27, 29, 33.[12] *Second*, as alleged, the products at issue in the 1980s litigations, which culminated in the Consent Judgment, were labeled only for use by adults. Am. Compl. ¶¶ 5–6. Indeed, the pleadings in the 1985 Litigation and the 1987 Litigation clearly referred to Adult Advil. Cendali Decl., Exs. 1–2; Am. Compl. ¶ 24. Moreover, as discussed above, all of Judge Conner's references to "Advil" in his written opinions refer to Adult Advil.[13] *Third*, as alleged, the advertisements at issue in the 1980s litigations concerned products labeled for use only in adults and the effectiveness of these products in adults. Am Compl. ¶ 6. This contemporaneous evidence underscores that the 1987 Litigation was initiated regarding and focused solely on advertising for Adult Advil and the effects of ibuprofen on adults.

McNeil argues that the Consent Judgment should be interpreted to include Pediatric Advil products because Judge Conner's decision relied exclusively on his findings regarding ibuprofen's mechanism of action, which McNeil says does not vary between adults and children. Def. Br. 15. McNeil's argument is based on two factual assertions, neither of which can be considered in resolving a motion to dismiss, and neither of which is correct.

McNeil mischaracterizes the 1980s Litigations by claiming that Judge Conner primarily based his findings on the mechanism of action of ibuprofen and acetaminophen, not clinical

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[12] For example, Judge Conner was presented with a clinical study on osteoarthritis that was conducted in connection with the NDA for Motrin. Cendali Ex. 4 (1985 Litigation Trial Tr.) at 114:15-118:20. Judge Conner also heard evidence about multiple endoscopic studies (*i.e.*, the Lanza Studies and Cohen Studies), which reported the effects of ibuprofen on the GI lining. *Id*. at 167:21-168:19.; *see also id.* at 592:12-594:8 (referencing George L. Royer, *et al.*, *Safety Profile: Fifteen Years of Clinical Experience with Ibuprofen*, 77 Am. J. Med. 25 (1984)).

[13] Judge Conner also refers to 200 mg tablets, which is the tablet size of the Advil product marketed to adults: "AHP sought to obtain FDA approval for OTC dosages of ibuprofen up to 1600 mg. per day (one-half the prescription daily maximum), but the FTC finally ruled that the OTC package instructions should specify a dosage of one or, if necessary, two 200 mg. tablets, with no more than six tablets, or 1200 mg., in any 24–hour period." *Am. Home Prods.*, 654 F. Supp. at 574.

data—in other words, on theories about how the medications work rather than clinical data about their actual effects on patients. Def. Br. 15. This is contrary to Pfizer's allegation that Judge Conner "relied upon conclusions based upon clinical data derived from use of, Adult Advil and Tylenol-branded products in adult populations only." Am. Compl. ¶ 53. As all of the allegations of Pfizer's Complaint must be accepted as true, that allegation is sufficient to defeat this argument. It is also contradicted by Judge Conner's decision that "[m]any hundreds of exhibits, filling eight file drawers, were received in evidence, most of them . . . *packed with numerical data* . . . ." 654 F. Supp. at 572 (emphasis added). *See also id*. at 584 (considering a "series of double-blind placebo-controlled clinical tests, some sponsored by McNeil and some by AHP, in which the patients reported, *inter alia*, on any adverse gastrointestinal symptoms").

Moreover, Judge Conner rejected the contention of McNeil's predecessor that he should consider *why* the medications resulted in different levels of side-effects (*i.e.*, the mechanism of action), rather than consider the actual data. At trial, McNeil proposed the "prostaglandin theory" as a mechanism-of-action theory about why ibuprofen purportedly caused upset stomachs in some patients. Cendali Decl. Ex. 4 (1985 Litigation Trial Tr.) at 908:16-21. When AHP sought to introduce testimony to rebut this theory, Judge Conner said the validity of the "prostaglandin theory"—or any theories about *why* side-effects occurred—was a non-issue. *Id.* at 916:10-14. Judge Conner explained that the only issue in the litigation was whether side-effects actually occurred. *Id.* at 914:4-5. Indeed, he further stated: "I couldn't care less, really, for purposes of this case, whether they're explainable." *Id.* at 913:25-914:2. In other words, Judge Conner did not rely on the mechanism of action theory in deciding the case. Thus, McNeil's assertion conflicts with both Pfizer's Amended Complaint and Judge Conner's opinion. In any event, if the Court deems this issue relevant to the interpretation of the Consent

Judgment, McNeil's claim about what Judge Conner did and did not rely on is, at best, a factual dispute that cannot be resolved on a motion to dismiss.

Further, there is no evidence before the Court to support McNeil's assertion that ibuprofen's mechanism of action will lead to the same physiological impacts in children as it does in adults. There were no findings to this effect in the 1980s litigation. Nor was any evidence on this point introduced.[14] The issue simply was not litigated. It would be improper to assume on this motion to dismiss—without any factual record—that ibuprofen affects adults and children the same way. In fact, discovery will reveal clinical studies showing that it does not. Accepting McNeil's argument would require this Court to make scientific pronouncements about children's physiology without the benefit of any facts regarding the issues that can impact the effects of ibuprofen and other medicines on their GI tract—including, for example, facts regarding the level of prostaglandins in children's bodies, their baseline levels of H. pylori bacteria, and the relative thickness of the mucosal lining of their stomachs.

It would be particularly improper to accept McNeil's assumption given that the FDA, as alleged by Pfizer, refused to extrapolate safety data from adults to approve ibuprofen for non-prescription use in children. Am. Compl. ¶¶ 8, 41. The FDA recognized that children are not "little adults" when it comes to assessing the adverse effects of medicine because the impact may differ considerably between pediatric and adult patients.[15] As alleged, the FDA would not accept

[14] McNeil argues that Pfizer's position means that the Consent Judgment should be limited by the particular demographics of the patients enrolled in the clinical studies admitted into evidence during the 1985 and 1987 litigations and should exclude "women, elderly patients, or members of particular ethnic or racial groups." Def. Br. 18. That is not the case. Pfizer's position is that the Consent Judgment is properly limited to the issues in the litigations from which it resulted—specifically Advil products that were approved and labeled for use in adults and clinical data about the relative effects of Advil on adults—and should not be expanded to pediatric products and populations that were not included in any of the evidence or arguments presented to Judge Conner.

[15] *See, e.g.*, Samuel M. Lesko & Allen A. Mitchell, *Renal Function After Short-term Ibuprofen Use in Infants and Children*, 100 PEDIATRICS 954, 954, 956 (1997) ("Renal failure has been reported after [NSAID] use in adults, but only rarely among children," possibly because "they are less likely than adults to have other factors predisposing to acute renal disorders (e.g., congestive heart failure, diuretic use, and chronic renal failure).").

safety data from clinical studies in adult populations or simply consider theories about ibuprofen's mechanism of action. Instead, the FDA required both Pfizer's predecessor and McNeil to conduct clinical studies in order to show that ibuprofen was safe for pediatric use before approving their respective New Drug Applications ("NDA") for OTC Children's Advil and Children's Motrin (both pediatric ibuprofen products), respectively.[16] *Id.* ¶ 8. Indeed, the data Pfizer presented to doctors in the Infants' Advil Ad is derived from the very study conducted by Pfizer's predecessor to meet the FDA's requirement.

McNeil attempts to bolster its premature argument by further relying on factual assertions that are outside the record. For example, McNeil asks this Court, on a motion to dismiss, to determine *the rationale underlying* the FDA's decision to require a class-wide warning concerning the risk of stomach bleeding on all non-steroidal anti-inflammatory drugs (NSAIDs) which ibuprofen is required to carry as a member of that class. As a threshold matter, *the class-wide warning label was not imposed until 2009—two decades after the Consent Judgment was entered in 1989*—and thus obviously can have no bearing on what the parties intended the term "Advil" to mean in the Consent Judgment. *See* Required Warnings and Other Labeling, 74 Fed. Reg. 61514 (Nov. 25, 2009) (Cendali Decl., Ex. 5). Further, the class-wide label says nothing about comparisons that can be made between products. For example, Judge Conner found that aspirin (another NSAID) causes a higher rate of adverse effects on the stomach than ibuprofen in adults, yet ibuprofen carries the exact same class warning as aspirin because they are both types

[16] The impropriety of McNeil's attempt to rush to judgment on this issue is underscored by the fact that studies among children and infants—such as the Boston University Fever Study sponsored by McNeil to support its NDA for Children's Motrin (Am. Compl. ¶ 41)—report no statistically significant difference between acetaminophen and ibuprofen with regard to adverse GI events. *See* Samuel M. Lesko, *The Safety of Ibuprofen Suspension in Children*, 135 INT'L J. CLINICAL PRACTICE 50, 50 (2003) ("There were no significant differences between the drugs in the risk of admission or the risk of secondary endpoints (. . . physician visits for abdominal pain or dyspepsia) . . . ."). *See also* Samuel M. Lesko & Allen A. Mitchell, *An Assessment of the Safety of Pediatric Ibuprofen*, 12 J. AM. MED. ASS'N 929, 929 (1999) ("[A]mong ibuprofen-treated children, the observed risk of [GI] bleeding . . . was not significantly different from the risk among acetaminophen-treated children.").

of NSAIDs. 654 F. Supp. at 584. Nor does the class-wide label indicate that children and adults experience the same degree of adverse effects from NSAIDs. Ultimately, however, if the Court deems this issue relevant, the resolution of this issue needs a fuller factual record, including evidence to support both parties' factual assertions on this point.

In sum, based on the plain language and above-referenced circumstances surrounding the formation of the Consent Judgment, the *only* reasonable interpretation is that the Consent Judgment does not include Pediatric Advil and thus McNeil's motion must be denied. *See Ambac Assur. Corp. v. Adelanto Pub. Util. Auth.*, 696 F. Supp. 2d 396, 403 (S.D.N.Y. 2010) (denying motion where plaintiff alleged the "only reasonable interpretation" of an agreement); *In re Rhythms NetConnections Inc.*, 300 B.R. 404, 410 (Bankr. S.D.N.Y. 2003) (denying motion where settlement order was unambiguous and defendants' interpretation was unreasonable).

B. Even if the Term "Advil" is Ambiguous, the Amended Complaint Alleges That the Parties Did Not Intend for It to Apply to Pediatric Products

Even if the Court were to find that the term "Advil" in the Consent Judgment is not unambiguously limited to Adult Advil, the term is, at most, ambiguous. An ambiguous contract can be interpreted only after a factual record is developed, and thus the issue cannot be resolved on a motion to dismiss. *See Bayerische Landesbank, N.Y. Branch v. Aladdin Capital Mgmt. LLC*, 692 F.3d 42, 56 (2d Cir. 2012) (holding that "in the context of a motion to dismiss, if a contract is ambiguous as applied to a particular set of facts, a court has insufficient data to dismiss a complaint for failure to state a claim") (internal quotation marks omitted); *Bank of N.Y. Trust, N.A. v. Franklin Advisors, Inc.*, 522 F. Supp. 2d 632, 637 (S.D.N.Y. 2007) ("The Court's role on a 12(b)(6) motion to dismiss is not to resolve contract ambiguities.").

In order to interpret ambiguous terms, the fact-finder "will examine the record as a whole in an effort to interpret the agreement so as to effectuate the intent of the parties." *Bank of N.Y.*

v. Amoco Oil Co., 35 F.3d 643, 661 (2d Cir. 1994); *see also Random House*, 150 F. Supp. 2d at 620 (considering the parties' intent in interpreting ambiguous contract). In determining the parties' intent, the fact-finder may consider extrinsic evidence, such as the negotiations and the parties' course of dealing. *See Canterbury Belts Ltd. v. Lane Walker Rudkin, Ltd.*, 869 F.2d 34, 38 (2d Cir. 1989) (considering evidence of the parties' negotiations in interpreting ambiguous consent decree); *McGraw-Hill v. Vanguard Index Trust*, 139 F. Supp. 2d 544, 555–56 (S.D.N.Y. 2001) (concluding, after examining extrinsic evidence, that neither party contemplated that the license at issue would encompass a financial instrument that did not exist at the time). In analyzing extrinsic evidence, "only objective manifestations of intent are relevant"—statements of subjective intention uncommunicated to the other party are immaterial in construing the terms of the contract. *Faulkner v. Nat'l Geographic Soc.*, 452 F. Supp. 2d 369, 377 (S.D.N.Y. 2006).

In its Amended Complaint, Pfizer alleges that "the parties . . . did not intend the 1989 Order to apply to the pediatric products." Am. Compl. ¶ 9. In support of this fact, Pfizer alleges that Pediatric Advil products did not exist on the market at the time, and no evidence about such products or their effects on children and infants were presented in the 1980s litigations. *Id.* ¶¶ 7–8, 27, 33, 40. If McNeil denies these allegations, it will have an opportunity to test them in discovery—but at this point, Pfizer's allegations must be accepted as true.

Moreover, the law is settled that when interpreting an ambiguous contract, courts should adopt the narrower of two conflicting interpretations unless there is a clear mutual intent to the contrary. *See Bank of N.Y.*, 35 F.3d at 662 ("Where one interpretation [of an ambiguous contract] is broader than another, courts should not apply the broader interpretation absent a clear manifestation of intent."); *Roswell Capital Partners LLC v. Alt. Constr. Techs.*, No. 08 Civ. 10647 (DLC), 2009 WL 497578, at *4 (S.D.N.Y. Feb. 27, 2009) ("The canon supporting

narrower interpretation when meaning is ambiguous also supports a narrower reading of the bond requirement here.") (citing *Bank of N.Y.*, 35 F.3d at 662); *Mandal v. City of N.Y.*, No. 02 Civ. 1234 (WHP) (FM), 2008 WL 754666, at *3 (S.D.N.Y. Mar. 17, 2008) ("[T]o the extent that the [agreement] is subject to two conflicting interpretations, the Court must adopt the narrower of the two possible interpretations."). Pfizer's allegations about the parties' intent show that the parties did not intend, or even contemplate, that "Advil" would encompass Children's Advil or Infants' Advil, or claims about the effects of such products on children under the age of 12.

In short, McNeil's motion should be denied because McNeil has not demonstrated (because it cannot) that the unambiguous language of the Consent Judgment includes Children's Advil. It does not; to the contrary, the plain language of the Consent Judgment favors Pfizer. If the Court believes there is ambiguity in the Consent Judgment, Pfizer is entitled to present the extrinsic evidence in its favor, and McNeil's motion should be denied for that reason as well.

C. Rule 60(b) Is Not Applicable

Finally, McNeil's claim that Pfizer must pursue a remedy through Rule 60(b) simply begs the question. Def. Br. 19. Rule 60(b) only applies to situations where there is a reason to modify an order *after the issue has been litigated and decided*. *Chao v. Russell P. Le Frois Builder, Inc.*, 291 F.3d 219, 229 (2d Cir. 2002) ("Rule 60(b) . . . only applies after a 'final judgment, order, or proceeding' occurs.") (quoting Fed. R. Civ. P. 60(b)). It does not apply to conduct that is not covered by the order at issue. And it does not apply to issues that have not been litigated in the first place. *See Mallet v. Miller*, 953 F. Supp. 2d 491, 493 (S.D.N.Y. 2013) ("[C]ourts have rejected Rule 60(b) motions raising . . . claims unrelated to the prior . . . proceeding."); *Pena v. Travis*, No. 1:03 Civ. 0564 (GLS) (RFT), 2005 WL 1843264, at *3 (N.D.N.Y. Aug. 2, 2005) (stating allegations about "new claims [that] are completely unrelated to the facts and theories in [the] original complaint . . . do not form a proper basis" for a Rule 60(b) motion).

In other words, for Rule 60(b) to apply here, McNeil must have first litigated the issue and obtained an order prohibiting Pfizer from claiming that ibuprofen is as safe on the stomachs of children and infants as acetaminophen. McNeil has not done so. Thus, Pfizer has no obligation to prove a reason that justifies relief from something that McNeil has never proven in the first place.

II. THE AMENDED COMPLAINT ALLEGES A JUSTICIABLE CONTROVERSY

The Declaratory Judgment Act requires a "substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality . . . ." *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotation marks omitted). The dispute must be "definite and concrete, touching the legal relations of parties having adverse legal interests," rather than based on "hypothetical" facts. *Id.*

This case presents a quintessential application of the Declaratory Judgment Act. Pfizer alleges that after it ran the Infants' Advil Ad, McNeil sent a letter demanding that Pfizer stop because the advertisement violated the Consent Judgment. Am. Compl. ¶¶ 12–13, 44. Those allegations alone are sufficient to demonstrate that a justiciable controversy exists. *Kickstarter v. Artistshare, Inc.*, No. 11 Civ. 6909 (PAC), 2012 WL 1192021, at *3–4 (S.D.N.Y. Apr. 10, 2012) (where plaintiff had already engaged in the allegedly infringing conduct, "there is no dispute that the controversy is sufficiently 'immediate' and 'real'").

But McNeil filed its original motion to dismiss, arguing Pfizer failed to allege that it had "'concrete' plans" to run advertisements "that would bring the parties into 'immediate' conflict"; "wants to run that specific ad again"; and was "engaged in meaningful preparation" to "rerun the 2013 ad." Dkt. 12 at 14–16. While Pfizer thought its original complaint was sufficient, it opted to avoid an unnecessary procedural dispute by adding the *express words* that McNeil claimed were needed. Specifically, Pfizer alleges in its Amended Complaint that it "intends to resume

running the Infants' Advil Ad" and "is prepared to re-run [it] once the risk of being held in contempt of the 1989 Order has been removed – indeed, the ad is obviously complete, and Pfizer is willing and able to place the ad for publication." Am. Compl. ¶ 15, 48. *See also id.* ¶ 47.

With these amendments, McNeil should have withdrawn its argument and moved on. McNeil now argues instead that the Amended Complaint fails to satisfy the "immediacy" requirement, but offers no reason why this is so. Def. Br. 20–21. As stated above, Pfizer has already created and run the Infants' Advil Ad and alleges that it will re-run the ad following the disposition of this action, which demonstrates an ongoing, immediate dispute. The only obstacle preventing Pfizer from re-running the ad is disposition of this action—a factor that does not preclude jurisdiction. *See Diamonds.net v. Idex Online, Ltd.*, 590 F. Supp. 2d 593, 599 (S.D.N.Y. 2008) (rejecting claim that plans were speculative and not immediate where impediment to launch of website was "the legal uncertainty" of infringement claim).[17]

The fact that Pfizer stopped running the Infants' Advil Ad does not defeat jurisdiction. The law is clear that where, as here, a party is coerced by a cease-and-desist letter to stop an activity under a threat of contempt or infringement, it can still seek relief under the Declaratory Judgment Act. "[A] party need not risk suit . . . by engaging in the identified activity before seeking a declaration of its legal rights." *AARP v. 200 Kelsey Assocs., LLC*, No. 06 Civ. 81 (SCR), 2009 WL 47499, at *6 (S.D.N.Y. Jan. 8, 2009); *see also Medimmune*, 549 U.S. at 129 (explaining the "dilemma posed by . . . coercion—putting the challenger to the choice between abandoning his rights or risking prosecution—is a dilemma that was the very purpose of the

[17] McNeil's suggestion that jurisdiction fails because Pfizer has not specified the exact date on which it intends to resume running the Infants' Advil Ad is meritless. Def. Br. 22. Pfizer does not know when this litigation will be resolved, and its Amended Complaint is sufficient because it alleges that Pfizer plans to re-run the Infants' Advil Ad and is poised to do so following declaratory judgment. *See Gelmart Indus., Inc. v. Eveready Battery Co.*, No. 13 Civ. 6310 (PKC), 2014 WL 1512036, at *5 (Apr. 15, 2014) ("It is sufficient that [plaintiff] has alleged that it solicited retailers, designed branding material, is capable of commencing manufacture of products within weeks, and was 'poised' to commence a product launch before [defendant] asserted infringement.").

Declaratory Judgment Act to ameliorate") (internal quotation marks omitted). The *AARP* court went on to say: "[S]o long as the '[t]he factual and legal dimensions of the dispute are well defined' . . . jurisdiction is not defeated by a party's decision to refrain from taking some action and thus 'make[ ] what would otherwise be an imminent threat [of suit] at least remote, if not nonexistent.'" 2009 WL 47499, at *6 (quoting *Medimmune*, 549 U.S. at 128).

Allegations regarding Pfizer's intention to re-run the Infants' Advil Ad are sufficient, in and of themselves, to satisfy the Declaratory Judgment Act. McNeil's focus on the sufficiency of allegations about "similar comparability claims" that Pfizer may run is a distraction. Def. Br. 21–22. The fact that Pfizer also pled that it plans to run *additional* ads that make similar claims for Children's and Infants' Advil simply adds to the totality of the circumstances showing a dispute between the parties. Further, McNeil's argument misconstrues the issue in this case. As noted above, Pfizer's claim involves the interpretation of the Consent Judgment and whether it applies across the board to all ads for Pediatric Advil products. It does not require the Court to determine the truth or falsity of any ad. Thus, allegations about future ads are not necessary to determine whether the parties have a real and immediate conflict now over the scope of the Consent Judgment. Def. Br. 21–22.[18]

CONCLUSION

Based on the foregoing, Pfizer respectfully requests that the Court deny McNeil's motion.

[18] McNeil's contention that the Court has no jurisdiction over Pfizer's *claim* because McNeil cannot allege a *counterclaim* for false advertising based on future advertising is baseless. Def. Br. 22. First, the viability of a *counterclaim* is not a factor in determining jurisdiction over a *claim* for declaratory judgment. *See Medimmune*, 549 U.S. at 127; *see also* 28 U.S.C. § 2201 (a court "may declare the rights and other legal relations of any interested party seeking such declaration, *whether or not further relief is or could be sought*") (emphasis added). Second, McNeil's argument ignores the fact that it could file a claim based on the existing Infants' Advil Ad.

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